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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,798	10/21/2003	Jay Edelberg	1676.001US2	5627
21186	7590	12/06/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			MALLARI, PATRICIA C	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/690,798

Applicant(s)

EDELBERG ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-76 and 78-84 is/are pending in the application.
- 4a) Of the above claim(s) 59-73, 77 and 85-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-76 and 78-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/24/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the sensor as claimed in claims 74-84 of the instant application must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 11/2/05 is acknowledged. The traversal is on the ground(s) that search and examination of both groups can be made without serious burden on the examiner since they are both classified in the same class and subclass. This is not found persuasive because, as stated in the previous Office action, the groups require different fields of search.

With respect to the election of species F, the applicants note that they are entitled to examination of a reasonable number of species and that "claim 74 is generic with regard to species F, 4, and 6" and "explicitly defines how the claimed species are related". The applicants fail to cite support for their entitlement to examination of a reasonable number of species. 37 CFR 1.141 states that more than one species may be *claimed* in one national application provided the application also includes an allowable claim generic to all the claimed species. Species E and F have no generic claims. No generic claim has as yet been found to be allowable with respect to species 3 and 4. With respect to claim 74 being "generic" to species F, 4, and 6, it is unclear what the applicants mean by such statement. The examiner stated in the previous Office action claim 74 is generic both to species 3 and 4 and to species 5 and 6. Neither the presence of a generic claim nor the fact that the species are somehow related fails to dispute the fact that distinct species are indeed encompassed by each group. The applicants further cite passages of the MPEP that discuss Markush groups. No election requirement was applied within a Markush-type claim, and so the recited passages are irrelevant.

The requirement is still deemed proper and is therefore made FINAL.

Claim 95-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Claims 59-73, 77, and 85-94 are further withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. The applicants timely traversed the restriction (election) requirement in the reply filed on 11/2/05. The applicants failed to identify the claims belonging to the elected species F. The examiner has determined that claims 74-84 belong to species F, and claim 78 belongs to species 4. Claims 59-73 and 85-94 have been withdrawn as belonging to nonelected species E, and claim 77 has been withdrawn as belonging to nonelected species 3.

The election requirement between species 5 and 6 has been removed, since the type of mammal into which the biosensor may be inserted is considered merely intended use language and as such fails to patentably distinguish the different species.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 79-82 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 79 recites the limitation, "wherein the biosensor is implanted or inserted in an animal". Claim 81 further recites that the animal is a human. The human body or any part thereof is considered non-statutory subject matter which cannot positively be claimed. To overcome this rejection, claim 79 should

read "The biosensor according to claim 74, wherein the biosensor is adapted to be implanted or inserted in an animal."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-76 and 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by 5,750,376 to Weiss et al. Weiss describes in vitro or ex vivo modified stem cells (col. 15, line 64-col. 23, line 5 of Weiss). The cells can be coupled via an electrical interface to endogenous tissue or cells, can be implanted into a mammalian subject at a site distant from a natural site for physiological or pathophysiological function of a subject (col. 22, lines 56-60; col. 23, lines 37-45 of Weiss), can monitor a chemical, physiological, or pathophysiological function of the subject, and can produce a coagulation factor, serotonin, a growth factor, a hormone, or a receptor (col. 22, lines 31-55 of Weiss). The applicants should note that the claim language fails to require positively that the cells actually perform or be arranged as described above, only that they *can* perform or be arranged accordingly. The cells as described by Weiss certainly can perform or be arranged to perform as described. Claims 75 and 78-82 merely comment further on the recited capabilities. Furthermore, the term "implantable physiological or pathophysiological biosensor" on line 1 of claim 74 is merely "intended

use" language which cannot be relied upon to define over the prior art, since Weiss teaches all of the claimed structural limitations and their recited relationships. See *Ex parte Masham 2 USPQ 2nd 1647*. The cells of Weiss are certainly capable of being used as such a sensor.

Regarding claim 76, the stem cells are molecularly, genetically, or cellularly engineered (col. 18, line 43-col. 23, line 5 of Weiss).

Regarding claim 83, the modified stem cells are incorporated within a device, wherein the device may include, for example a substrate (example 11 of Weiss) or an injection cannula or needle (example 14 of Weiss).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,377,721 to Walt et al. in view of US Patent NO. 5,750,376 to Weiss et al. Walt teaches a biosensor array useful for drug screening and which can employ virtually any cell type or size, including stem cells, wherein the biosensor array further includes a tube in to which the cells are placed (col. 9, lines 10-26; col. 10, lines 33-50; col. 12, lines 25-36; col. 15, lines 13-55 of Walt). Walt fails to specifically recite modified stem cells being used in the sensor.

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However, Weiss teaches modified stem cells that may be used for drug screening (col. 30, lines 20-col. 34, line 55; col. 57, lines 40-55 of Weiss). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use modified stem cells in the biosensor array of Walt since Walt teaches that the array is useful for drug screening and that any cell type may be used, including stem cells, and Weiss teaches that modified stem cells are appropriate cell types for use in drug screening.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 5,958,767 to Snyder et al.

US Patent No. 5,981,268 to Kovacs et al.

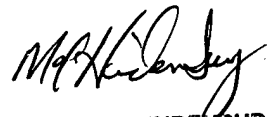
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Patricia Mallari
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